

### REMARKS

Claims 1-3, 5-8, 16-21, and 23-26, and 33-36 are pending. Claims 13-14 and 31-32 are withdrawn. Claims 4 and 22 were previously canceled. Claims 9-12, 15, and 27-30 are canceled by this communication.

#### Rejection under 35 U.S.C. §112

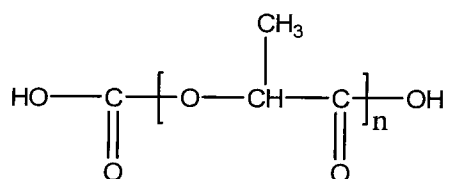
Claims 1-3, 5-8, 16-21, and 23-26, and 33-36 are rejected under 35 U.S.C. §112, first paragraph as lacking sufficient support for the hydrolyzed poly(lactic acid) (PLA) or a block copolymer having two terminal hydroxyl groups. Applicants respectfully point to formulae (III), (IV), and (V) as described in the specification, which are hydrolyzed PLA polymer or block copolymer having two terminal hydroxyl groups. The limitation -- a hydrolyzed poly(lactic acid) (PLA) or a block copolymer having two terminal hydroxyl groups -- is thus sufficiently described in the specification.

Regardless, Applicants believe the amendment to the claims renders the above rejections moot.

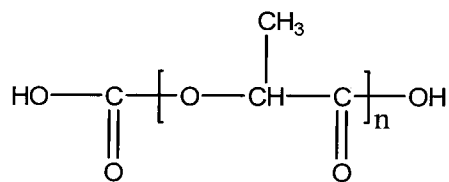
#### Rejections under 35 U.S.C. § 102

Claims 1-3, 5-8, 16-21, 23-26, and 33-36 are rejected under 35 U.S.C. 102 (b) as being anticipated by Yang et al. (US 6,258,121 B1) and the teachings of Kim et al. (U.S. Patent No. 5,548,035) ("Kim") incorporated by Yang.

Claim 1 now defines a medical article comprising an implantable substrate having a coating. The coating includes a polymer comprising **a derivative of carboxylated poly(lactic acid) or a block-copolymer having at least one moiety comprising a derivative of carboxylated poly(lactic acid)**. Note, a carboxylated poly(lactic acid) has a structure of:



Yang describes a coating that can include a poly(lactic acid)-co-poly(ethylene oxide) (PLA-PEO) co-polymer. Kim describes PLA-PEO-PLA tri-block copolymer. Yang and Kim



fail to teach a coating having a polymer comprising

Accordingly, claim 1 is patentably allowable over Yang under 35 U.S.C. §102(b). Claims 2, 3, 5-8, and 16-18 depend from claim 1 and are patentably allowable over Yang under 35 U.S.C. §102(b) for at least the same reason.

Claim 19 defines a method for forming a coating having features similar to the coating in claim 1. For the reasons above, claim 19 is patentably allowable over Yang under 35 U.S.C. §102(b). Claims 20, 21, 23-26 and 34-36 depend from claim 19 and are patentably allowable over Yang under 35 U.S.C. §102(b) for at least the same reason.

Claim 33 further defines the method of claim 19 as further including the following acts:

**(a) hydrolyzing the diblock-copolymers and triblock-copolymers to obtain hydrolyzed block-copolymers of poly(lactic acid) and poly(ethylene glycol), and (b) incorporating the hydrolyzed block-copolymers of poly(lactic acid) and poly(ethylene glycol) into the coating.**

Both Yang and Kim fail to teach the acts provided by claim 19 and these two additional acts defined by claim 33. Accordingly, claim 33 is patentably allowable over Yang under 35 U.S.C. §102(b).

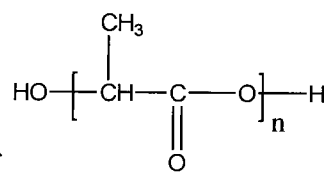
#### Rejections under 35 USC § 103

Claims 1-3, 5-8, 16-21, 23-26, and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang (US 6,258,121B1) in view of Okada (US 6,113,943).

As discussed above, claim 1 describes a medical device having a coating including a polymer comprising a derivative of carboxylated poly(lactic acid) or a block-copolymer having

at least one moiety comprising a derivative of carboxylated poly(lactic acid). Yang does not describe or teach this feature of the coating in claim 1. As described at page 11, lines 18-21, a coating having a polymer comprising carboxylated poly(lactic acid) can accelerate the degradation rate of the coating, which, as described at page 3, lines 12-14, can be very desirable.

Okada describes a sustained-release preparation of hydrolyzed polymer of lactic acid having average molecular weight of 25,000 to 60,000 Daltons for releasing physiologically active substance. To a person of ordinary skill in the art, a hydrolyzed polymer of lactic acid



has a general formula of  $\text{HO}-\left[\text{CH}(\text{CH}_3)-\text{C}(=\text{O})-\text{O}\right]_n-\text{H}$ . This polymer is clearly different from the one defined by claim 1. Okada fails to describe or teach a coating having a polymer comprising carboxylated poly(lactic acid). Accordingly, Yang and Okada in combination do not teach a medical device having a coating as defined by claim 1. Claim 1 is therefore patentably allowable over Yang in view of Okada under 35 U.S.C. 103(a). Claims 2, 3, 5-12, and 15-18 depend from claim 1 and are patentably allowable over Yang in view of Okada under 35 U.S.C. §103(a) for at least the same reason.

Claim 19 defines a method for fabricating a medical article having a coating. The coating includes a polymer or a copolymer similar to the polymer or copolymer as defined by claim 1. As seen from the discussion of claim 1, Yang and Okada together do not teach this polymer or copolymer. Accordingly, claim 19 is patentably allowable over Yang in view of Okada under 35 U.S.C. §103(a). Claims 20, 21, 23-30, and 33-36 depend from claim 19 and are patentably allowable over Yang in view of Okada under 35 U.S.C. §103(a) for at least the same reason.

The undersigned authorizes the examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.

### **CONCLUSION**

Withdrawal of the rejection and allowance of the claims are respectfully requested. **If the Examiner has any suggestions or amendments to the claims to place the claims in condition for allowance, applicant would prefer a telephone call to the undersigned attorney for approval of an Examiner's amendment.** If the Examiner has any questions or concerns, the

Examiner is invited to telephone the undersigned attorney at (415) 393-9885.

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Respectfully submitted,

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